

RESOLUTION

Whereas the Clinical Laboratory Improvement Advisory Committee (CLIAC) is specifically charged to advise the Secretary on issues related to the implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), including test categorization and waiver determination, and;

Whereas the Clinical Laboratory Improvement Advisory Committee (CLIAC) has heard compelling concerns from multiple stakeholders about the performance of waived tests and the process of determination of test waiver; and

Whereas the Clinical Laboratory Improvement Advisory Committee (CLIAC) recognizes the need to urgently but thoroughly and fairly address these concerns in a fashion that best serves the interest of the health of the public;

Be it resolved that the Clinical Laboratory Improvement Advisory Committee (CLIAC), in the interests of the public health, will convene a workgroup, including CLIAC representation, to:

- 1) review the concerns of key stakeholders, including the device manufacturing industry, laboratory medicine professionals, physician office laboratories, health care consumers, and the agencies responsible for administration of the Clinical Laboratory Improvement Amendments;**
- 2) review data on the process of waiver determination and performance of waived tests and any other relevant information;**
- 3) recommend to CLIAC appropriate changes to process of waiver determination and oversight of waived tests that assure:**
 - i. clear guidelines for waiver determination**
 - ii. guidelines for waiver determination that are based on good scientific evidence reflecting the likely performance and impact of waived devices in their sites of actual use**
 - iii. clear guidelines for the labeling of waived test devices that include information on relevant pre-analytic, analytic, post-analytic factors that may impact the result of the test or the impact of its use**
 - iv. guidelines for the oversight of the performance of waived tests that assure that the Department has regular, accurate data on the performance of these tests and the appropriate information to address concerns about problematic performance**
 - v. an approach to waiver determination and oversight that balances the needs of key stakeholders and protects the health of the public;**
- 4) report its findings to CLIAC at its regular meeting in February 2004.**